K01 0691

MAY - 8 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

(As required by 21 CFR 807.92)

1. General Information

Classification:	Class II Magnetic Resonance Imaging (MRI) System
Common/Usual Name: Proprietary Name:	Magnetic Resonance Imaging (MRI) Option Blood Oxygenation Level Dependent (BOLD) Option for MR Systems
Establishment Registration:	Marconi Medical Systems, Inc. World Headquarters 595 Miner Road Highland Heights, Ohio 44143 Contact: Duane Praschan Phone: (440) 483-3000 FDA Owner Number: #1580240 FDA Registration Number: #1525965
Performance Standards:	No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act.

2. Intended Uses

The Blood Oxygenation Level Dependent (BOLD) Option is intended for use in acquiring and analyzing images created using the sequences optimized to produce BOLD contrast. The analysis package is useful in quantifying small susceptibility changes in the human brain, created by the execution of specific tasks.

3. Device Description

Marconi's BOLD Option uses EPI sequences combined with post-processing software to allow users to acquire images with BOLD contrast and perform image analysis. This analysis may include image co-registration, motion correction, statistical analysis of activation, division of datasets based upon description of experiment paradigms, fusion of different types of images and color coding. The sequences used during acquisition are similar to those originally described in Marconi's 510(k) submission K954646. This optional software functionality is designed for use with Marconi's 1.5T Infinion and Eclipse magnetic resonance (MR) systems with software versions VIA 2.0E or higher.

4. Safety and Effectiveness

This optional functionality is similar to the Philips BOLD Analysis Package and the Siemens BOLD MRI Package in technological characteristics and intended use. The following substantial equivalence chart has been provided to demonstrate the equivalence

of this option with these predicate devices.

Substantial Equivalence Chart

Parameter	Marconi BOLD Option for the Infinion and Eclipse 1.5T Systems	Predicate Devices – Philips BOLD Analysis (K990329), Siemens BOLD MRI (K984221).
System Compatibility	1.5T Edge Eclipse	Easy Vision Workstation and Gyroscan NT system (K990329)
Sequences	EPI sequences.	Dynamic, Multislice T2*-weighted sequences with Single or Multi-Shot FFE or FFE-EPI methods (K990329)
Acquisition Options	Low and high spatial resolution.	High temporal resolution (K990329)
Image co-registration	Same.	Parametric images can be overlaid on anatomical images (K984221)
Motion correction	Uses an Automated Image Registration (AIR) method to combine images and register all scans in a group.	Unknown based on available literature.
Statistical analysis of activation	Same.	Standard statistical analysis to analyze BOLD data (K990329)
Dataset analysis	Datasets automatically divided based on user-defined experimental paradigms.	Unknown based on available literature.
Fusion	Software includes ability to combine two images into one. The user can define the percentage each image contributes to the fused image.	Unknown based on available literature.
Color coding	Same.	Processing with color over-lays (K990329).
Intended Use and Indications for Use	The BOLD Option is intended for use in acquiring and analyzing images created using the sequences optimized to produce BOLD contrast. The analysis package is useful in quantifying small susceptibility changes in the human brain created by the execution of specific tasks.	The BOLD Analysis option for the EasyVision is intended for use in analyzing images created using the BOLD function of the Gyroscan NT system. The BOLD Analysis option is useful in qualifying small susceptibility changes in the human brain created by the execution of specific tasks. (K990329)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2001

Mr. Duane Praschan
Marconi Medical Systems, Inc.
595 Miner Road
HIGHLAND HEIGHTS OH 44143

Re: K010691
Blood Oxygenation Level Dependent (BOLD) Option
Dated: February 23, 2001
Received: March 8, 2001
Regulatory Class: II
21 CFR §892.1000/Procode: 90 LNH

Dear Mr. Praschan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K01 0691

Device Name: Blood Oxygenation Level Dependent (BOLD) Option

Indications for Use:

The Blood Oxygenation Level Dependent (BOLD) Option for MR Systems is intended for use in acquiring and analyzing images created using the sequences optimized to produce BOLD contrast. The analysis package is useful in quantifying small susceptibility changes in the human brain created by the execution of specific tasks.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010691

Prescription Use √ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)